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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/200,119 11/25/98 AHMED

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EXAMINER

HM12/0414

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PESELEV, E

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

04/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/15/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-9 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (Lancet, vol. 342, pages 453-456 (1993)) or Thylefors (Who Drug Information) in combination with Hauske et (U.S. Patent No. 4,512,982) for the reasons set forth in the Office Action of September 13, 1999.

Applicant's arguments filed March 13, 2000 have been fully considered but they are not persuasive.

Applicant contends that the topical administration disclosed by Hauske et al refers to sterilization of sick-room utensils and as industrial microbial. This argument has not been found persuasive. Hauske et al in column 9, lines 24-35 discloses the use of azithromycin derivatives in combination with a pharmaceutically-acceptable carrier or diluent, for example in the form of ointments and creams. Thus, Hauske et al clearly suggest intended topical application of azithromycin derivative to animals, including humans. Topical application of azithromycin to the eye would have been prima facie obvious from the teachings by the prior art.

Claims 4-6 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bailey et al, Thylefors or Hauske et al.

Each of Bailey et al, Thylefors and Hauske et al discloses pharmaceutical compositions containing azithromycin. The claimed compositions are anticipated by the art of record. Further, if there are differences in the amounts of azithromycin used, it would have been within the ordinary skill in the art at the time of the instant invention to adjust the optimal amount of the active ingredient in a composition.

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Applicant's arguments filed March 13, 2000 have been fully considered but they are not persuasive.

In response to applicant's arguments, the recitation of topical application in the preamble has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over First Meeting of the WHO Alliance For The Global Elimination of Trachoma, Geneva, 30 June-1 Jule 1997).

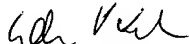
The First Meeting suggests the use of azithromycin for the topical treatment of trachoma in the eye. The claimed methods and compositions are anticipated by First Meeting. Further, it would have been prima facie obvious to a person having ordinary skill in the art to combine azithromycin with conventional carriers for topical application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peslev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 9.30 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200